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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/657,144 | 09/09/2003 | David Alexander | IMMR-IMD0002E | 1898 |
| 22903 | 7590 | 06/29/2006 | EXAMINER | |
| COOLEY GODWARD LLP ATTN: PATENT GROUP THE BOWEN BUILDING 875 15TH STREET, N.W. SUITE 800 WASHINGTON, DC 20005-2221 | | | STOICA, MARIA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3715 | |
| DATE MAILED: 06/29/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,144

Applicant(s)

ALEXANDER ET AL.

Examiner

Maria Stoica

Art Unit

3715

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17, 21-25 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 26-27 and 30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

Claims 1-16 and 18-20 are cancelled. Claims 17 and 21-31 are pending.

Allowable Subject Matter

1. Prosecution on the merits of this application is reopened on claims 17, 21-25 and 28-30 are considered unpatentable for the reasons indicated below:

Regarding claims 17 and 28-29, these claims lack clarity in one of the limitations presented. Please refer to the 35 USC 112 rejection below.

Regarding claims 21-25 and 30, upon an updated search and study of the admitted prior art, a new rejection is considered appropriate on the patentability of these claims.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 102 as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the

first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/923,477, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for all the claims of this application. The prior filed application bears no mention of, among other features, the retainer and ring configuration or of a pivotable mock anatomical site. As such, the application has been given a date of 28 January 1998 commensurate with the filing of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17 and 28-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The phrase "coupled to and spaced apart from" is not precisely described. It is unclear how a first item may be *both* coupled to and spaced apart from a second item *at the same time*, when these terms seem to be opposites of each other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 21-25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (US Patent No. 5,828,197) in view of Lang et al. (US Patent No. 5,480,307).

Regarding claim 21, Martin discloses a method comprising inserting a peripheral device into a guide tube (col. 15, lines 14-16), the guide tube being disposed within a resilient material (col. 15, lines 20-21), the resilient material being configured to simulate feedback forces as the peripheral device is received in the guide tube (col. 15, lines 29-30, 42-45). Martin further discloses a mock anatomical site with an orifice (Figure 5). Martin does not expressly disclose that the mock anatomical site can be pivoted to a desired position relative to a housing or that it can be locked in a desired position using a locking assembly coupled to the pivoting mechanism. However, Lang discloses a similar mock anatomical site for simulations, where the mock anatomical site can be pivoted by the user to a desired position, and can subsequently be locked in that position (col. 7, line 65 – col. 8, line 6). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Lang into the method of Martin in order to allow the user flexibility in setting up the apparatus correctly for any given procedure, and in order to allow for a more realistic simulation of the actual procedure.

Regarding claim 22, the method steps of claim 21 are intended to simulate a medical procedure using the mock anatomical site as a point of entry into a simulated body (Abstracts of both references).

Regarding claims 23 and 30, both Lang and Martin teach that the mock anatomical site is a mock face (Figure 5 of Martin, Figure 1 of Lang). Furthermore, regarding claim 23, Lang teaches that the pivoting includes pivoting the face to a position simulating an individual lying down (Figure 10).

Regarding claim 24, Martin discloses a housing (74), a resiliency-providing material disposed proximate to an orifice and the housing (col. 15, lines 20-21); and a hollow member extending through the resiliency material and between the orifice and the housing, the hollow member configured to guide a peripheral device from the orifice into the housing (Figure 5a). The hollow member in this instance is interpreted to be the area of the nostril 76, as well as the "nasal cavity" modeled by the head model (74), since these areas serve the purpose of guiding the inserted object into the housing. Martin does not expressly disclose that the mock anatomical site can be pivoted to a desired position relative to a housing. However, Lang discloses a similar mock anatomical site for simulations, in which the mock anatomical site can be pivoted by the user to a desired position (col. 7, line 65 – col. 8, line 6). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Lang into the apparatus of Martin in order to allow the user flexibility in setting up the

apparatus correctly for any given procedure, and in order to allow for a more realistic simulation of the actual procedure.

Regarding claim 25, neither Martin nor Lang expressly disclose that the resilient material is a block of foam. However, since no advantage has been provided for using foam as opposed to any other material to model the resiliency material, the choice of such a material is considered merely a matter of Design Choice and is not considered patentably distinguishable from the invention of the prior art. It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate any specific material into the invention of Martin, as modified by Lang, depending on the simulation result desired.

Response to Amendment

5. Although the examiner has previously indicated claims 17 and 21-31 as allowable, the examiner notes that no official agreement was reached over the phone when the applicant contacted the examiner about the amendment the applicant intended to submit. The examiner did acknowledge that it would be acceptable for the applicant to cancel the rejected claims.

Allowable Subject Matter

6. Claims 26-27 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Regarding claims 26-27, the

ring configured to rotate about a retainer was not found in any of the prior art documents of record. Regarding claim 31, the pivotable torsion tube in combination with a mock anatomical site was not found in any of the relevant prior art.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Stoica whose telephone number is (571) 272-5564. The examiner can normally be reached on M-F: 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on (571) 272-6788. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


KATHLEEN MOSSER
PRIMARY EXAMINER